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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,287	08/16/2001	Stan Hazen	26473/04195	2235

24024 7590 04/21/2004

CALFEE HALTER & GRISWOLD, LLP  
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CLEVELAND, OH 44114

EXAMINER
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NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/931,287

**Applicant(s)**

HAZEN ET AL.

**Examiner**

Patrick J. Nolan

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-17 and 21-32 is/are pending in the application.  
4a) Of the above claim(s) 16,17,21-24,26-32,34 and 36 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 15,25,33 and 35 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1-22-02, 10-24-03.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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1. Claims 15-17 and 21-36 are pending.
2. Applicant's election without traverse of Group I, claims 15-17 and 23-36, species, a peptide containing 3-bromotyrosine, in the Paper received 1-26-04 is acknowledged. Claims 16-17, 21-24, 26-32, 34 and 36 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

It is noted that claims 27, 29, 34 and 36 drawn to combinations of the species will be considered when there is an allowable species.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by U. S. Patent No. 5,602,099.

The '099 patent teaches a peptide containing 3-bromotyrosine, see SEQ ID NO. 14, in particular, wherein said peptide is an opioid receptor antagonist..

The claimed invention is anticipated by the prior art teachings.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 15, 25, 33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,602,099 in view of U. S. Patent 6,319,686.

The '099 patent has been discussed previously.

The claimed invention differs from the prior art teaching by the recitation of a peptide containing a heavy isotope labeled 3-bromotyrosine, wherein said label is  $^2\text{H}$ ,  $^{13}\text{C}$ ,  $^{15}\text{N}$ ,  $^{13}\text{C}_6$ .

However, the '686 patent teaches that it is generally desirable to employ a system wherein one can measure the ability of an antagonist to effect an opioid receptor by using techniques well known in the art such as isotopically labeled reagents (the antagonist would be one), such as  $^2\text{H}$ ,  $^{13}\text{C}$ , or  $^{15}\text{N}$  in a screening assay (see column 37, in particular). Therefore it would have been obvious to one of skill in the art at the time the invention was made to be motivated to isotopically label the peptide taught by '099 patent with any well known isotope such as  $^2\text{H}$ ,  $^{13}\text{C}$ ,  $^{15}\text{N}$ , to screen for receptor binding as taught by the '686 patent, since it is desirable to be able to measure antagonist receptor interaction, as taught by the '686 patent. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

6. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

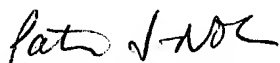
7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

A handwritten signature in black ink, appearing to read "Patrick J. Nolan".

Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

4/17/2004